IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY BRIEF IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

Plaintiffs' opposition fails to respond to most of the reliability challenges posed by Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon). Instead, they focus on Dr. Walmsley's qualifications, cite to distinguishable case law, and discuss irrelevant literature. Plaintiffs' arguments should be rejected.

ARGUMENTS AND AUTHORITIES

I. Despite His Qualifications, Dr. Walmsley's Opinions Offered in *This* Case Must be the Result of a Reliable Methodology.

No matter how qualified Dr. Walmsley may be "he must still base his opinions on a reliable, scientific method." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 680 (S.D.W. Va. 2014); *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *6 (S.D.W. Va. Sept. 29, 2014) ("Qualifications alone do not guarantee reliability.").

And just because this Court found different opinions offered by Dr. Walmsley to be admissible in different cases does not mean that the opinions he seeks to offer here are automatically admissible. Indeed, this Court has made clear that it will not tolerate "misuse of [its] previous *Daubert* rulings." *See, e.g.*, *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *4 (S.D.W. Va. Apr. 24, 2015). When faced with a different record

and different arguments, as is the case here, the Court is merely "informed—though not bound—" by its previous rulings. *Id*. at *18.

II. Plaintiffs Point to No Evidence Showing That Dr. Walmsley's General Opinions Are the Result of a Reliable Methodology.

A. Dr. Walmsley's informed-consent opinions are unsupported.

Ethicon acknowledges that this Court has permitted other experts to testify generally as to the adequacy of IFUs. But the warnings opinions Dr. Walmsley seeks to offer here are unlike those offered in the cases Plaintiffs rely upon.

In *Carlson v. Boston Scientific Corp.*, for example, the Court allowed Dr. Shull to give an opinion based on risks he perceived in practice that he claimed were not contained in the product's IFU. *Carlson*, No. 2:13–cv–05475, 2015 WL 1931311, at *15-16 (S.D.W. Va. Apr. 28, 2015). Dr. Walmsley here is not offering that kind of warnings opinion. Instead, he seeks to testify that the IFUs were "not sufficient to enable informed consent." Ex. B to Defs.' Mot. (Dkt. 1998-2), Walmsley Report, Gen. Op. 1; Ex. C to Defs.' Mot. (Dkt. 1998-3), Walmsley Report, Gen. Op. 1. As Ethicon pointed out in its Memorandum in Support, these kinds of "informed consent" opinions lack a reliable basis when the expert makes no showing that the unreferenced complications should have been included in the IFU. *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 542-43 (S.D. W. Va. 2014); *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *35-36 (S.D. W. Va. Sept. 29, 2014).

Plaintiffs claim that *Tyree* and *Sanchez* do not apply because Dr. Walmsley is not being offered as a regulatory expert as Dr. Pence was in those cases. *See* Pls.' Opp'n (Dkt. 2171) at 4-5. But Plaintiffs fail to recognize that Dr. Pence's opinions were excluded because she relied on various publications and literature that did not go the heart of her opinion. Instead, the literature and publications she relied upon merely demonstrated that complications could occur with the

product, but did not provide guidance on whether those complications should be included in the IFU. *See Tyree*, 54 F. Supp. 3d at 542; *Sanchez*, 2014 WL 4851989, at *35.

This is precisely what happened here. Dr. Walmsley referenced several articles, but did not tie any of them to his opinions regarding informed consent. Indeed, when specifically asked the basis of his opinion on informed consent he cited only his "clinical experience"; he made no attempt to link it to the literature. *See* Ex. D to Defs.' Mot. (Dkt. 1998-4), Walmsley 3/23/16 Dep. Tr. 42:19-43:2. This Court has excluded expert opinion testimony when the expert fails to identify specific sources that support the expert's opinion. *Carlson*, 2015 WL 1931311, at *20 (excluding expert's opinion where expert claimed to rely on clinical experience and scientific literature but failed to explain how these sources "substantiate[d] his opinion").

And even the literature Plaintiffs claim supports Dr. Walmsley opinions here is no support at all. They contend that a 2014 study by Sara Abbott addresses informed consent and the consent decision-making process. *See* Pls.' Opp'n (Dkt. 2171) at 4; *see also* Ex. E to Defs.' Mot. (Dkt. 1998-5), S. Abbott, *Evaluation and management of complication from synthetic mesh after pelvic reconstructive surgery: a multicenter study*, Am. J. Obstet. Gynecol., 210(2):163 e1-8 (2014). Not only does this study fail to address what should be contained in an IFU (*see* Defs.' Mem. (Dkt. 1999) at 3), a study reported on in 2014 cannot support what IFUs should have provided in 2002 and 2010. This article provides no basis for Dr. Walmsley's general opinions here. And although Plaintiffs claim that Dr. Walmsley relied on "numerous other studies" (Pls.' Opp'n (Dkt. 2171) at 4 n.2), he does not make any connection to those studies in rendering his opinions. Nor do Plaintiffs make any attempt to show the Court that Dr. Walmsley did so.

B. Plaintiffs apparently withdraw Dr. Walmsley's safer-alternative opinion but attempt to transform it into something it is not.

Dr. Walmsley stated in both reports that "[s]afer alternatives[,] designs[,] and procedures existed in 2002 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy." Ex. B to Defs.' Mot. (Dkt. 1998-2), Walmsley Report at 13; Ex. C. to Defs.' Mot. (Dkt. 1998-3). But shortly thereafter in the *Fox* report he added:

> In 2002, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Fox was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the TVT IFU inherent to the risks of using synthetic mesh as an alternative to autologous fascia. As such, Dr. Warner was unable to warn Ms. Fox of the subsequent complications she has suffered from.

Ex. B to Defs.' Mot. (Dkt. 1998-2), Walmsley Report at 13.

Plaintiffs now claim that what Dr. Walmsley stated in his Report is not what he meant. They claim Ethicon is "assuming" that Dr. Walmsley "intends to offer an opinion that alternative treatments for SUI should have been included in the TVT IFU." Pls. Opp'n (Dkt. 2171) at 5. But Ethicon made that assumption because that was exactly what Dr. Walmsley said in his Report in *Fox* excerpted above.

Even so, Plaintiffs now appear to be withdrawing Dr. Walmsley's safer-alternative opinion. They claim that "Dr. Walmsley does not have an opinion that alternatives should have been discussed in the IFU." *Id.* They even had Dr. Walmsley execute an affidavit to that effect. Ex. E to Pls.' Mem. (Dkt. 2171-6).[1] But despite that concession, Plaintiffs claim that Dr.

[1] General Opinion No. 2 in *Ridgley* is different because Dr. Walmsley offers no opinion on informed consent but only that he disagrees with Dr. Mutone's (the implanting surgeon) choice of procedures. Ex. C to Defs.' Mot. (Dkt. 1998-3), Walmsley Report at 8-9; see also Defs.' Mem. (Dkt. 1998) at 5 n.1. Dr. Walmsley's statements with respect to Dr. Mutone have no evidentiary value and should be barred for that reason. Indeed, Dr. Mutone did not rely on the IFU in the care of Ms. Ridgley. Ex. 1, Walmsley 3/23/16 Dep. Tr. 50:24-51:5.

Walmsley's opinion is something it is not. They now claim that Dr. Walmsley's opinion is simply the first sentence of his General Opinion No. 2—i.e., that "[s]afer alternative designs and procedures existed in 2002" and that these alternative procedures carried "lesser risk[s]." Pls.' Opp'n (Dkt. 2171) at 6.

Ethicon acknowledges that the Court permitted Dr. Walmsley to offer this opinion in *Eghnayem*, 57 F. Supp. 3d at 714-715. But as this Court cautioned in *Winebarger* and more recently in *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, *16 (S.D.W. Va. Apr. 28, 2016), when faced with a different record and different arguments, the Court is merely "informed—though not bound"—by its previous rulings. In *Eghnayem*, Dr. Walmsley supported his opinion with literature, including the Nygaard study. *Eghnayem*, 57 F. Supp. 3d at 714. Not only is that study not cited here, but the only support offered in *Fox* is testimony from Dr. Haverkorn, one of Ms. Fox's doctors, that the autologous procedure was available in 2002 and was "safe." Ex. B to Defs.' Mot. (Dkt. 1998-2), Walmsley Report at 12. There was no mention that the procedure was "safer," nor was there any comparison of TVT's safety to safety of other vaginal mesh products. There is no other basis offered in support of this sentence in *Fox*.

Likewise in *Ridgley*, Dr. Walmsley offers no basis for vague General Opinion No. 2—he simply disagrees with the choice of procedure even though he agreed that TVT was the standard of care in 2010. Ex. 1, Walmsley 3/23/16 Dep. Tr. 56:19-22. Without a basis for his opinion, it is simply *ipse dixit* and should be excluded.

Even so, evidence of alternative *surgical procedures* for the treatment of pelvic organ prolapse is irrelevant to state of the art and cannot support a claim for design defect. *See Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting plaintiff's theory that defendant's

spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because "[t]he fact that an alternative method of surgical hernia repair was potentially available does not support Plaintiff's design defect claim"); *Bogle v. Sofamor Danek Group, Inc.*, No. 95–8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any *particular* defect with the product. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently. . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon."); *see also Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and noninstrumental spinal repair, not a defect in the product itself).

At bottom, alternative surgical techniques, including those using native tissue, are not alternative feasible designs. *See, e.g.*, *Linsley v. C.R. Bard, Inc.*, No. 98-2007, 2000 WL 343358, at *3 (E.D. La. Mar. 30, 2000) (granting summary judgment where expert had "merely show[n] that . . . there existed 'alternative techniques' for repairing a ventral hernia using Marlex Mesh, and not . . . an alternative design"); *Schmidt*, 2013 WL 3802804, at *2 ("[N]on-mesh repair is not an alternative design and does not meet Plaintiff's burden to support [a design defect claim]."); *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 256 (5th Cir. 1999) (finding surgical alternatives that do not use pedicle screws cannot be considered "alternative designs"); *Hornbeck v. Danek Med., Inc.*, No. 99-30966, 2000 WL 1028981, at *1 (5th Cir. July 5, 2000), 226 F.3d 641 (Table)

(noting that "alternative methods of treatment are not alternative designs"); *Toll v. Smith & Nephew Richards, Inc.*, No. 95-442, 1998 WL 398062, at *2 (E.D. La. July 14, 1998) ("Plaintiffs have only suggested alternative methods of [surgery] which utilize the System's already existing components; plaintiffs have not established an alternative design to the System. The component parts of the System remain the same.").

Thus, even as limited, Dr. Walmsley's "safer alternative" opinions cannot support any claim for design defect and can be excluded on relevancy grounds.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Konstantin Walmsley, M.D., for the reasons stated above and in its memorandum in support of its motion.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Telephone: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Telephone: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on May 16, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com